

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re application of:

Madaline Chirica, et al.

Appli. No.: 10/667,290
(U.S. Pat. No. 7,411,041)

Filed: September 18, 2003

For: DCRS5 POLYPEPTIDES

Examiner: J. Seharaseyon

Art Unit: 1647

Conf. No.: 8667

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**STATEMENT OF THE CORRECT PATENT TERM ADJUSTMENT: GROUNDS UNDER
37 C.F.R. § 1.702 FOR THE ADJUSTMENT (37 C.F.R. § 1.705 (b)(2)(i) TO (iv))**

Sir:

1. This statement is being submitted in support of the "REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT INDICATED ON PATENT UNDER 37 C.F.R. § 1.705(d) " to which this statement is attached.

37 C.F.R. § 1.705 (b)(2)(i)

2. The patent term adjustment (PTA) shown on U.S. Patent No. 7,411,041 is 672 days. Applicants believe that this determination of 672 days is in error, due to the Office's improper interpretation of the PTA provisions as discussed in *Wyeth et al. v. Dudas*, No. 07-1492 (D.D.C. September 30, 2008). Specifically, the Office improperly limited PTA to either the PTA as calculated under 35 U.S.C. §154(b)(1)(A) or as calculated under 35 U.S.C. §154(b)(1)(B), but not both. 69 Fed. Reg. 34238 (June 21, 2004). However, as discussed in *Wyeth et al. v. Dudas*, the statute requires that PTA may comprise contributions from both 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B), and that the Office's interpretation of the statute was erroneous to the extent that it considered any delays within the first three years after filing the application

to “overlap” with delays under §154(b)(1)(B) after three years from the filing of the application. According to the Court, no delay accumulated within the first three years after the filing date can be said to “overlap” with delays under §154(b)(1)(B), which by definition do not arise until after three years from the filing date. It is respectfully submitted that the correct patent term adjustment under 37 C.F.R. § 1.702, as calculated under the analysis of *Wyeth et al. v. Dudas*, is **996 days**.

37 C.F.R. § 1.705 (b)(2)(ii)

3. The basis on which Applicants seek adjustment is as follows, which is based on the analysis laid out in *Wyeth et al. v. Dudas*, rather than the Office’s analysis laid out in 69 Fed. Reg. 34238 (June 21, 2004). Accordingly, the net PTA comprises accumulated PTA arising from both 35 U.S.C. §154(b)(1)(A) and (B), excluding actual overlap (35 U.S.C. §154(b)(2)(A)), and deducting any periods of time in which Applicants failed to engage in reasonable efforts to conclude prosecution (35 U.S.C. §154(b)(2)(C)(i)).

A. The application was filed, along with a Preliminary Amendment cancelling all original claims 1 – 23 and adding new claims 24 – 38, on September 18, 2003.

B. A first Restriction Requirement was mailed May 15, 2006 based on the original (cancelled) claim set, not the claims actually pending at the time.

C. Applicants pointed out the error in a response dated August 15, 2006.

D. The Examiner expressly vacated the May 15, 2006 Restriction Requirement and issued a new Restriction Requirement in an action mailed November 1, 2006.

E. A first Notice of Allowance was sent on June 26, 2007, along with a notice that the patent term adjustment would be 543 days, mistakenly based on the vacated first Restriction Requirement, rather than the second Restriction Requirement.

- F. Applicants filed an RCE with an IDS on September 21, 2007.
- G. A second Notice of Allowance was sent on October 3, 2007, along with a notice that the patent term adjustment would be 543 days.
- H. Applicants filed a first Application for Patent Term Adjustment and Statement of the Correct Patent Term Adjustment on December 20, 2007.
- I. Applicants paid the issue fee on December 21, 2007.
- J. Applicants filed a Petition to Withdraw From Issue, an RCE, and an IDS on January 31, 2008.
- K. Applicants' first Application for Patent Term Adjustment was **held in abeyance** in a paper dated February 20, 2008.
- L. A third Notice of Allowance was sent on March 11, 2008, along with a notice that the patent term adjustment would be 543 days.
- M. Applicants filed a second Application for Patent Term Adjustment on June 6, 2008, requesting that the PTA be calculated based on the difference between the filing date of September 18, 2003 and the date of the first action (second Restriction Requirement) on November 1, 2006, less 14 months, i.e. **713 days**.
- N. The Office issued a response titled "On Application for Patent Term Adjustment" on July 7, 2008, granting in part Applicants' second Application for Patent Term Adjustment. The response accepts Applicants' arguments, but asserts that there was a period of Applicant delay under 37 C.F.R. § 1.702(c)(10) when Applicants submitted an RCE and IDS on January 31, 2008 after the mailing of the Notice of Allowance on October 3, 2007. Accordingly, the Office asserted that the **41 day** period between the submission of the RCE and IDS on January 31, 2008, and the date of

mailing of second Notice of Allowance on March 11, 2008, constituted Applicant delay to be deducted from the PTA.

O. Accordingly, the PTA listed on the face of U.S. Patent No. 7,411,041 when it issued on Aug. 12, 2008, was **672 days** (713 days – 41 days). This PTA was calculated under 35 U.S.C. §154(b)(1)(A), and excluded any PTA calculated under 35 U.S.C. §154(b)(1)(B) under the Office's interpretation of the PTA rules and statutes.

P. In light of the analysis laid out in *Wyeth et al. v. Dudas*, the correct PTA should have also included delay under 35 U.S.C. §154(b)(1)(B), less any overlap between 35 U.S.C. §154(b)(1)(A) and (B) periods.

i) Delay under §154(b)(1)(B) is the period starting the day after the date that is three years after the filing date and ending on the issue date, except that such PTA no longer accrues after the filing of an RCE (35 C.F.R. §702(b)(1)). Accordingly, for the present application, the resulting §154(b)(1)(B) period runs from the period starting the day after the date that is three years after the filing date (September 19, 2006) and ending on the date the first RCE was filed (September 21, 2007), or **368 days**.

ii) The 713 day delay under §154(b)(1)(A) overlaps with 368 day delay under §154(b)(1)(B) to the extent that it extends beyond the date that is three years from the filing date, or 44 days. See §154(b)(2)(A) as interpreted in *Wyeth et al. v. Dudas*. The resulting non-overlapping delay period under §154(b)(1)(A) is 713 – 44, or **669 days**.

iii) The resulting net PTA is the sum of the non-overlapping delays under §154(b)(1)(A) and (B), less the Applicant delay alleged in the "On Application for Patent Term Adjustment" dated July 7, 2008, or $669 + 368 - 41 =$ **996 days**.

Q. Accordingly, Applicants request that the PTA for U.S. Patent No. 7,411,041 be amended to **996 days**.

37 C.F.R. § 1.705 (b)(2)(iii)

4. The present application is not subject to a Terminal Disclaimer.

37 C.F.R. § 1.705 (b)(2)(iv)

5. The Office issued a response titled "On Application for Patent Term Adjustment" on July 7, 2008, granting in part Applicants' second Application for Patent Term Adjustment, and asserting that there was a period of Applicant delay under 37 C.F.R. § 1.704(c)(10) when Applicants submitted an RCE and IDS on January 31, 2008 after the mailing of the Notice of Allowance on October 3, 2007. Accordingly, the Office asserted that the **41 day** period between the submission of the RCE and IDS on January 31, 2008, and the date of mailing of second Notice of Allowance on March 11, 2008, constituted Applicant delay to be deducted from the PTA.

In summary, Applicants request that the PTA of 672 days listed on U.S. Patent No. 7,411,041 be amended to add delay under §154(b)(2)(B), as cut-off by filing of the first RCE, and as reduced by overlap with the period under §154(b)(2)(A). Applicants respectfully request a favorable decision on the patent term adjustment of **996 days** in this case.

Respectfully submitted,

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